K093902

Fresenius 2008T Hemodialysis Machines

Special 510(k) Notification: Device Modification

This 510(k) Summary is in accordance with the requirements of 21CFR Part 807.92

MAY 2 7 2010

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	920 Winter Street Waltham, MA 02451
Phone:	1-781-699-4475
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Contact Person:	Janet Kay, Director of Regulatory Affairs-Devices
Date of Preparation:	December 21, 2009

B. Device Name: Fresenius 2008T Hemodialysis Machine

Common Name: Hemodialysis Machine

Product Code/Classification Panel: 78 KDI / Gastroenterology/Urology

Classification: Class II per § 876.5860

C. Legally Marketed Predicate Device (unmodified devices):

Fresenius 2008T Hemodialysis Machine

D. Device Description:

1. The optional CDX modification incorporates a standard Windows/Linux capable computer (PC board) into the 2008T giving clinics the option to load data management software into the machine. With data management software on the machine the user may then interface with the program, using the machines preexisting alphanumeric keyboard, then transfer treatment data directly from the 2008T machine to their In-center medical information system.

2. Additionally, the selection of Citrasate® (K000792) and DRYalysate® (K980659) acid concentrates have been added to the selection of acid concentrates available to our customers on the 2008T hemodialysis machine. The user interface has been changed to allow the user to

select Citrasate/DRYalysate from the dialysis screen of the 2008T hemodialysis machine and to display the proper constituents of the concentrate.

E. Indications for Use:

The Fresenius 2008T is indicated for acute and chronic dialysis therapy.

Substantial Equivalence Decision Making Process

1. **Is the product a device?**

YES - The modified Fresenius 2008T Hemodialysis Machine is a device pursuant to 21 CFR §201 [321] (h).

2. **Does the new device have the same intended use?**

YES – The intended use for the modified 2008T Hemodialysis Machine is identical to that for the unmodified 2008T (K080964) as follows:

Intended Use

The Fresenius 2008T is indicated for acute and chronic hemodialysis

3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

NO – The Fresenius 2008T with CDX option is a modified version of the Fresenius 2008T Dialysate Delivery System. The performance and technological characteristics of the modified Fresenius 2008T are equivalent to those of the Fresenius 2008T (K080964) Dialysate Delivery System and raise no new types of safety or effectiveness questions.

4. **Does descriptive or performance information demonstrate equivalence?**

YES – Fresenius Medical Care North America believes the information provided in this submission clearly describes the modified Fresenius 2008T and demonstrates that it is substantially equivalent to the original Fresenius 2008T Dialysate Delivery system.

F. Safety Summary

The Fresenius 2008T hemodialysis machine with CDX option incorporates a standard Windows/Linux capable computer (PC board) into the machine. Additionally, Citrasate/DRYalysate was added to the 2008T's selectable acid concentrates. All water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines,

and language options remain unchanged from the predicate device, the 2008T (K080964). A Risk Analysis has been completed and potential hazards associated with the modifications have been identified, mitigated and where applicable mitigations have been verified. All potential risks were deemed acceptable after mitigation.

G. Summary of non-clinical tests submitted with the premarket notification of the device

1. Full system validation and software regression testing was performed to ensure that the modifications to the 2008T hemodialysis functions as intended and that the modifications did not negatively impact the overall 2008T hemodialysis machine system. Testing included:

    - Software validation and regression testing
    - Electromagnetic compatibility (EMC) testing
    - Electrical safety testing
    - System performance testing using Citrasate® acid concentrate

    The results from the testing demonstrated that all modifications functioned as intended and met pre-determined acceptance criteria.

2. Electromagnetic compatibility testing (EMC) was conducted according to the IEC 60601-1-2 (2007) Class A Testing at CKC Laboratories, Inc. The modified 2008T hemodialysis machine, outlined in this submission, met the requirements for IEC 60601-1-2 devices.

3. Electrical safety testing was conducted according to the following standards:

    - UL 60601-1, 1st Edition,2006-04-26, (Medical Electrical Equipment, Part 1:General Requirements for Safety)
    - CAN/CSA-C22.2 No. 601.1-M90, 2005, (Medical Equipment Electrical Equipment, Part 1: General Requirements for Safety)

    The modified 2008T hemodialysis machine with was found to comply with the above standards.

H. General Safety and Effectiveness Concerns

Operators of the 2008T Hemodialysis machine with CDX option must be trained to administer hemodialysis at the direction of a physician. In addition, the operator should be:

- Knowledgeable of hemodialysis methodology and relevant physiology.
- Proficient in healthcare procedures regarding aseptic techniques.

- Thoroughly familiar with the contents of the Operator's manual.

Fully trained and qualified to operate this machine, and able to distinguish between normal and abnormal operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

Ms. Janet C. Kay
Director of Regulatory Affairs
Renal Therapies Group
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451

MAY 2 7 2010

Re: K093902
Trade/Device Name: Fresenius 2008T Hemodialysis Machine
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 27, 2010
Received: April 28, 2010

Dear Ms. Kay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093902

Device Name: Fresenius 2008T Hemodialysis Machine

Indications for Use:

Fresenius 2008T is indicated for acute and chronic dialysis therapy

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093902